

Market Applicability							
Market	DC	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X	NA

Mavenclad (cladribine)

Override(s)	Approval Duration
Prior Authorization	1 year

Medications	Quantity Limit
Mavenclad (cladribine) tablets	May be subject to quantity limit

APPROVAL CRITERIA

Requests for Mavenclad (cladribine) may be approved if the following criteria is met:

- I. Individual has a diagnosis of relapsing multiple sclerosis (RMS), including relapsing-remitting disease and active secondary progressive disease; **AND**
- II. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response or intolerance to at least one alternative drug indicated for the treatment of multiple sclerosis;

AND

- III. Individual has been on Mavenclad (cladribine); **OR**
- IV. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response or intolerance to one of the following:
 - A. Avonex (interferon beta-1a); **OR**
 - B. Rebif (interferon beta-1a); **OR**
 - C. Betaseron (interferon beta-1b); **OR**
 - D. Extavia (interferon beta1-1b); **OR**
 - E. Tecfidera (dimethyl fumarate); **OR**
 - F. Glatopa (glatiramer);
- OR**
- V. Individual has active secondary progressive multiple sclerosis (confirmed Expanded Disability Status Scale (EDSS) progression in the previous two years) who has tried (medication samples/coupons/discount cards are excluded from consideration as a trial) and had an inadequate response or intolerance to Mayzent.

Mavenclad (cladribine) may **not** be approved for the following:

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

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- I. Concurrent use with other MS disease modifying agents (such as Aubagio, Gilenya, Mayzent, Tecfidera, Tysabri, Lemtrada, Ocrevus, Copaxone/Glatopa, Extavia, Rebif, Avonex, Plegridy, or Betaseron); **OR**
- II. Individual with clinically isolated syndrome (CIS); **OR**
- III. Individual with current malignancy; **OR**
- IV. Individual with human immunodeficiency virus (HIV) infection; **OR**
- V. Individual with an active chronic infection; **OR**
- VI. Individual with moderate to severe renal impairment (creatinine clearance less than 60 mL/min); **OR**
- VII. Individual with moderate to severe hepatic impairment (Child-Pugh class B or C); **OR**
- VIII. Individual has completed two treatment courses (two years) of Mavenclad therapy.

Note:

Mavenclad has black box warnings for malignancy and risk of teratogenicity. Mavenclad may increase the risk of malignancy and is contraindicated in individuals with current malignancy. In individuals with prior malignancy or with increased risk of malignancy, evaluate the benefits and risks of Mavenclad therapy on an individual basis. Mavenclad is also contraindicated in pregnant women and in women and men of reproductive potential who do not plan to use effective contraception because of the risk of fetal harm. Exclude pregnancy before starting Mavenclad in females of reproductive potential. Advise females and males of reproductive potential to use effective contraception during Mavenclad dosing and for 6 months after the last dose in each treatment course. Stop Mavenclad if the individual becomes pregnant.

State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

Key References:

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: April 22, 2019.
2. Devonshire V, Havrdova E, Radue EW, et al. Relapse and disability outcomes in patients with multiple sclerosis treated with fingolimod: subgroup analyses of the double-blind, randomised, placebo-controlled FREEDOMS study. *Lancet Neurol.* 2012; 11:420-28. DOI: [http://dx.doi.org/10.1016/S1474-4422\(12\)70056-X](http://dx.doi.org/10.1016/S1474-4422(12)70056-X).
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2019; Updated periodically.
5. Olek MJ, Gonzalez-Scarano F, Dashe JF. Clinical presentation, course and prognosis of multiple sclerosis in adults. Last updated June 28, 2018. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Accessed: June 29, 2018.

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Applicable	X	X	X	X	X	X	NA

6. Rae-Grant A, Day GS, Marrie RA, et al. Practice guideline recommendations summary: Disease-modifying therapies for adults with multiple sclerosis. Report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology. *Neurology*. 2018; 90: 777-788. Available from <https://www.aan.com/Guidelines/home/GuidelineDetail/898>. Accessed: June 28, 2018.

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